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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,800

01/12/2006

Mark Bride

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EXAMINER

BOR, HELENE CATHERINE

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,800	<b>Applicant(s)</b> BRIDE, MARK	
	<b>Examiner</b> HELENE BOR	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/19/2008 has been entered.

#### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: Part (c) reads "which transmit light in said preselected wavelengths" should be --which transmits light in said preselected wavelengths--. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

4. Claims 1-6 & 9-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In Claim 1, the following phrase, "when an examination is not being performed", lacks support in the disclosure for defining the normal level of illumination within the examination room and thus improperly

incorporates new matter into the claims. The Specification states, Page 2, Line 9-10, "...such examination calls for darkening the room in which the examination is conducted" but not for when an examination is not being performed. In Claim 10, the following phrase, "only filtered by a single lens", was not previously disclosed in the Specification or the Claims and thus improperly incorporates new matter into the claims. The Specification states, Page 4, Line 12-14, "The examining clinician then dons a pair of spectacles provided with lens", however, no disclosure to only filtered by a single lens. In Claim 13, the following, "a single filter corresponding to each eye of an examiner" lacks support and adds structure elements to the disclosure that was not originally disclosed in the Specification or the Claims and thus improperly incorporates new matter into the claims. The Specification states, Page 4, Line 12-14, "The examining clinician then dons a pair of spectacles provided with lens", however, no disclosure to only a single filter.

***Claim Rejections - 35 USC § 102***

5. Claim 1-2 & 6 rejected under 35 U.S.C. 102(b) as being anticipated by Crane et al (US Patent No. 6,230,046).

**Claim 1-2:** Crane teaches a method of screening epithelial tissue for possible abnormal tissue sites (Col. 3, Line 15-17 & Col. 4, Line 18-24). Crane teaches providing ambient light from a normal illumination source at a normal level (Col. 10, Line 66 - Col. 11, Line 8). Crane teaches without reducing the ambient light from the normal level and illuminating a gross anatomical area of epithelial tissue with a preselected wavelength that selectively aids in visualizing abnormal tissue sites on gross area using reflected

light (Col. 2, Line 19-20 & 66-68, Col. 3, Line 1-6 & Col. 4, Line 21-26 & 38-47). Crane teaches the light source being from a chemiluminescent light source (Col. 4, Line 25). Crane teaches viewing the gross area through a filter lens which transmits light in a preselected wavelength while substantially blocking transmission of light of wavelengths other than the preselected wavelength including ambient light (Col. 4, Line 65 - Col. 5, Line 1 & Claim 3) to enhance the visualization of any of said abnormal tissue sites in the presence of the normal ambient light (Col. 1, Line 18-20, Col. 4, Line 42-44 & Col. 5, Line 28-31).

**Claim 6:** Crane teaches the abnormal epithelial tissue includes tumor phenotypes (Col. 4, Line 18-26)

***Claim Rejections - 35 USC § 103***

6. Claim 1-2, 5 & 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esparza et al. (US Patent No. 5,519,208) and further in view of Lonky (US Patent No. 5,329,938).

**Claim 1-2 & 10-13:** Esparza teaches illuminating a gross anatomical area of epithelial tissue with a light (Col. 3, Line 49-51) of preselected wavelengths [400-900 nm] that selectively aids in visualizing abnormal tissue sites. Esparza teaches viewing the gross anatomical area through a filter lens (Figure 1, Element 38) which transmits light in the same preselected wavelengths (Col. 3, Line 57-59). Esparza teaches substantially blocking transmission of light wavelengths other than said preselected wavelengths to enhance the visualization of the tissue sites (Col. 2, Line 66 - Col. 3, Line 2). Esparza teaches the light source being a lamp (Col. 2, Line 61). Esparza fails to teach the light

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source being chemiluminescent and detecting abnormalities, however, Lonky teaches the chemiluminescent light source being a favorable improvement over lamps because of lack of a power cord or batteries, does not produce heat and distributes light through the tissue being observed rather than focuses light at a specified location (Col. 1, Line 59-68). It would have been obvious to one of ordinary skill in the art to replace the lamp of Esparza with the chemiluminescent light source as taught by Lonkey for portable, cool, distributed light (Col. 1, Line 59-68). Further Lonky teaches using the chemiluminescent examination method for detecting various cellular abnormalities such as irregular vasculature and lesions (Col. 6, Line 46-48) for improved patient examinations (Col 4, Line 28-33). It would have been obvious to one of ordinary skill in the art to implement the method of Esparza and include abnormality detection as taught by Lonky for improved patient examinations (Col 4, Line 28-33). Esparza teaches providing spectacles wherein the reflected light is only filtered by a single lens on its path to the examiner's eye (Figure 5, Element 18).

**Claim 5:** Esparza teaches at least one preselected wavelength is from about 400 nm to about 600 nm (Col. 3, Line 53).

**Claim 9:** Esparza fails to teach the method with the first, second and third wavelength. However, Lonkey teaches a method wherein at least one preselected wavelength comprising a first wavelength of about 450 nm, a second wavelength of about 550 nm, and a third wavelength of about 600 nm (Col. 4, Line 48-52) in order emanate or elicit white light (Col. 4, Line 48-52). It would have been obvious to one of ordinary skill in the

art to combine the system of Esparza with the chemiluminescent light source as taught by Lonky in order emanate or elicit white light (Col. 4, Line 48-52).

7. Claim 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crane et al. (US Patent No. 6,230,046) as applied to claim 1-2 & 6 above, and further in view of Lonky (US Patent No. 5,329,938).

**Claim 3:** Crane fails to teach the light being white. However, Lonkey teaches various anomalies which display white light (Col. 8, Line 22-50). It would have been obvious to one of ordinary skill in the art to combine the teachings of Crane and Lonkey in order to provide a more accurate detection of problems in the region to be examined (Col. 8, Line 20-21). It would have been obvious to one of ordinary skill in the art to add the method of detecting white light as taught by Lonky to the method of Crane in order to provide a more accurate detection of problems in the region to be examined (Col. 8, Line 20-21).

**Claim 4:** Crane teaches wherein the method based on the filtered light, performing a visualization of the area for abnormal structures (Col. 4, Line 18-26) and the system and method is for enhanced invasive surgical procedures (Col. 10, Line 63-64), however, Crane fails to further describe the specific invasive surgical procedure such as tissue biopsy. Lonkey teaches an illumination method and discloses the need to biopsy the visual detectable abnormality to provide more accurate detection of problems (Col. 8, Line 17-21). It would have been obvious to one of ordinary skill in the art to add the method of tissue biopsy as taught by Lonky to the method of Crane in order to provide a more accurate detection of problems in the region to be examined (Col. 8, Line 20-21).

***Response to Arguments***

8. Applicant's arguments with respect to claim 1-6 & 9-13 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./  
Examiner, Art Unit 3768

/Eric F Winakur/  
Primary Examiner, Art Unit 3768